U/BR15

10/518022 DT05 Rec'd PCT/PTQ 1 5 DEC 2004

WO 03/107721

15

20

ELECTRICAL HEATING DEVICE PARTICULARLY FOR HEATING A PATIENT BODY

FIELD OF THE INVENTION

The present invention is generally in the field of electrical heating techniques, and relates to an electrical heating unit and a heating device and system utilizing the same. The present invention is particularly useful for heating a body, for example, in medical applications for heating a patient's body.

BACKGROUND OF THE INVENTION

Various medical applications, for example during a surgical procedure and within a certain time period thereafter, a patient's body requires to be externally heated, and preferably also uniformly heated. Heat transfer devices for transferring heat to the patient's body, which are used at present in operating rooms, are generally of two types: the first type utilizes a closed circuit with heated water circulating thereinside, and the second utilizes an open circuit, wherein heated air blows around the patient's body.

The heating technique of the first kind involves covering a patient with a thin rubber cover, with warm water circulating through the cover. A device, equipped with a heat exchanger and pump, warms and circulates the water. Some of these devices also have the capability of regulating the temperature of the water based on core temperature measurement. These systems, however, give off heat to the environment and cause discomfort to the medical team. Moreover, these systems suffer from the following drawbacks: the very high cost of warming units, occasional leaking as the result of cutting the unit, blocking of the system when a patient is too heavy, and the system being bulky and heavy (containing about 3.5-5 liters of water).

As for the technique of the second type, it utilizes force air warming. These systems can be mostly preset at one of three thermal levels up to 43°C. They have different configurations to fit the upper body, lower body, torso, and full body, as well as pediatric blankets. The warm air in the system escapes through the pores on the upper part of the blanket as well as through the flexible tubes into the theatre area, affecting the operating team and causing a certain degree of inconvenience. The energy suppliers can operate only one warming blanket at a time. Therefore, in most surgeries, either only the lower or the upper part of the body can be warmed by the system.

Intraoperative warming is needed during most operative procedures lasting longer than 30 minutes, and in all operations on children weighing less than 15 kilograms. The only situation where warming is practically not needed, are short procedures (less than 30 minutes), and when the temperature of the patient's body is intentionally lowered. Most patients begin losing body heat either prior to anesthesia or immediately upon the induction of anesthesia. Much body heat is lost within an hour of the start of anesthesia. Therefore, warming must begin either before or immediately following the induction of anesthesia.

10

15

20

One of the problems of intraoperative warming is associated with the requirements for servo-controlled delivery of heat, aimed at preventing overheating and allowing for the increased delivery of warmth to patients who are continuously losing body heat. Another problem is associated with the need for the circumferential warming of limbs, warming of discontinuous areas of the body and the possibility of warming sterile areas of the operative field. It is desirable to place a heating device on individual parts of the patient's body, so as to cover most of the body surface and to prevent the further loss of heat. Additionally, it is desirable to prevent the fan distribution of the warm air, and, while warming the desired parts of the patient's body, to prevent the warming of surgeons, nurses and anesthesiologists present at the time.

15

20

25

30

Comparing electrical heating to the above-described technique, the electrical heating has evident advantages, such as the possibility of the continuous control of heating, including computer control and automatic management.

U.S. Patent No. 4,532,410 discloses an electrical heating device for providing a feeling of warmth to the entire human body for comfort and protection in active outdoors pursuits in cold environments by means of conventional, convenient, practical and desirable materials such as a neck scarf. A heater is disposed in an appendage or bib attached to and made as an integral part of the neck scarf. The heater is composed of a heating element made of Nichrome sandwiched between two covering elements made of a heat diffusible material such as triacetate tape.

The use of electrical heating in operating rooms needs to guarantee the following three complex tasks:

- 1. It should guarantee electrical safety, namely, completely stave off the damage of the electrical voltage, especially taking into account that various solutions are in use during an operation, the presence of various metal instruments, the patient is undressed, as well as the possibility of hemorrhaging.
- 2. It should guarantee to avert the danger of burns that could be caused by the local overheating of heating elements.
- 3. It should guarantee the absence of the influence of the electromagnetic effects on electronic equipment involved in the operation or located in the vicinity of the heating device.

It is important to understand that in most cases, the above three tasks have to be accomplished together and completely. For example, to avoid the damage of electrical voltage, voltages as low as possible must be used. However, the use of low voltages with the required power compels the operation to take place with a high current, while this increase in current might affect the electronics located in the vicinity of the heating device.

To decrease the influence of the electromagnetic field of an electric power source onto the functioning electronics, it is known to utilize a bifilar arrangement

20

of conductors. This technique is disclosed for example, in the patent document DE29610436. However, this technique unavoidably leads to local heating, owing to the fact that the conductors in which heat required for heating an object (e.g., a patient's body) is dissipated, are located very close to each other.

5 SUMMARY OF THE INVENTION

There is a need in the art to facilitate the technique of electrical heating of an object, by providing a novel electrical heating unit and heating device and system utilizing the same.

The term "object" used herein signifies any subject as well as part of a human or animal body.

The present invention provides for electrical heating of an object with substantially homogeneous temperature field within the heating object. A heating unit according to the present invention can provide an as low as desired temperature gradient between the temperature of the heat-dissipating surface and the required temperature of the object, and can provide for compensating (reducing) a magnetic field created by the electrical heating unit in operation to be practically negligible, to meet the standard requirements and be even below the standard values.

A heating unit of the present invention comprises a heater element formed with internal or external heat distributor. A heating unit providing for compensating a magnetic field created by the electrical heating unit in operation can be fabricated from two elements, one made of a material with relatively high specific resistivity (e.g., stainless steel or transformer steel) and serving as a heater, and the other made from a material with relatively low specific resistivity (e.g. aluminum) serving as a heat-diffuser, thereby enabling using the elements in the form of short and wide strips, the fabrication method thereby being simple, with high accuracy of assembling. Such a heating unit is disclosed in WO 01/72249 assigned to the assignee of the present application.

However, it appears that for various applications, for example, heating a patient's body, e.g., in an operating room, the heating unit has to be as thin as possible, and flexible, and preferably also light.

5

10

15

20

25

30

According to one approach of the present invention, a thin and flexible heating unit satisfying the above conditions is obtained by making the heating unit from two functionally different adjacent elements electrically insulated from each other (e.g., each covered by a thin insulating layer, e.g., lacquer, or a laminating layer such as PVC, polypropylene, etc.) each being made from a metal foil with a low specific resistivity of about 0.015-0.1 Ohm·mm²/m, such as aluminum, copper, etc., the two elements having different resistance and different surface areas. That element, which is to be located closer to the object to be heated, has a relatively larger surface area and a relatively lower resistance as compared to the other element and serves as a distributor of heat (external distributor) created by the other element. Similarly, if compensation of a magnetic field is required, the element with a relatively larger resistance is in the form of a strip folded in a serpentine- or ripple-like fashion such that the length of each of the two adjacent substantially parallel segments of the strip is significantly larger than the length of the connecting segment between them. In order to avoid local heating that could lead to burns, the surface of the heating unit through which heat is transferred to the object, i.e., the surface of the heat-distributor, should preferably be substantially equal to the surface area of the object to be heated. The operation of the heating unit thus provides for reducing the density of the heat flow that reaches the surface of the object to be heated and provides uniform heat transfer to the surface area to be heated.

According to another approach of the present invention, all the above conditions are achieved by making the heating unit from a heater element with internal heat distributor. Such a heater element is made of an electrically conductive material and is made with holes so as to provide a desired value of a working resistance of the heater element and thereby having a relatively reduced effective cross-section. This results in substantially homogeneous temperature field in the

10

15

20

25

30

vicinity of the heater element, when operated (an electric current passes through the heater element). If compensation of a magnetic field is required, the heater element with holes is in the form of a strip folded in a serpentine- or ripple-like fashion such that the length of each of the two adjacent substantially parallel segments of the strip is significantly larger than the length of the connecting segment between them.

Thus, according to one aspect of the present invention, there is provided an electrical heating unit for use in a heating device for heating an object to a required temperature and enabling to maintain this temperature of the object, the heating unit having one of the following configurations:

- (i) comprises first and second elements each made of a material with a specific resistivity in a range of about 0.01-0.10hm·mm²/m thereby enabling substantial flatness and flexibility of the heating unit, the first and second elements being accommodated adjacent to each other in spaced-apart substantially parallel planes, being electrically insulated from each other, and having different resistance and different surface areas as compared to each other, the first element having the relatively high resistance and relatively low surface area and serving as a heater, and the second element, which is to be located closer to the object when in operation of the heating unit, serving as a distributor of heat created by the first element when the first element is connected to a power source, the heating unit being arranged so as to provide for compensating a magnetic field created by the heating unit when connected to the power source;
- (ii) comprises a heater element made of an electrically conductive material and formed with spaced-apart holes of predetermined shape and distribution within the heater element plane so as to provide a desired value of a working resistance of the heater element for generating a required heat power, the heating unit when connected to the power source thereby providing substantially homogeneous temperature field in the vicinity of the heating unit.

20

25

The different resistance of the two elements can be achieved by making them of different geometries (i.e., shape and dimensions) and/or making them from different materials. For example, both the heater and the heat-distributor elements may be made of the same material (e.g., aluminum), wherein the heater is a flat strip folded in a serpentine- or ripple-like fashion and the heat-distributor is of a flat sheet-like geometry. In this case, in order to provide compensation of the magnetic field when only the heater element is connected to the power source, the heater strip is folded such that the length of each of the two adjacent substantially parallel segments of the strip is significantly larger than the length of the connecting segment between them. In another example, the heat distributor element and the heater have a sheet-like geometry with the same perimeters, but the heater element is made with holes thereby having a relatively reduced effective cross-section. In this case, in order to reduce the magnetic field created by the heating unit to be practically negligible, the heat-distributor element is also connected to the power source such that the electric current in the two elements have the same magnitudes and opposite directions. The heater element and the heat-distributor element can be connected in series to the common power source. Generally, each of the two elements can be associated with its own power source. The power source may include an accumulator.

Thus, in one embodiment of the two-element heating unit of the invention, the heat-distributor element is a flat flexible sheet (e.g., of a substantially rectangular shape) and is to be disconnected from the power source ("passive" heat distributor). In this case, the heater element is a flat strip folded in a serpentine- or ripple-like fashion with the length of two adjacent segments of the strip being significantly larger than that of the connecting segment between them. According to another embodiment, the heat-distributor is also intended for connection to the power source ("active" heat distributor). In this case, the heat-distributor and the heater elements are shaped and connected to the power source such that the electric currents therein are of the same magnitudes and opposite directions, for example

the heater and heat-distributor elements have the same perimeters and the heater element is formed with holes.

The heating unit may include an additional external "passive" heat-distributor. This additional passive heat-distributor element is accommodated closer to the body to be heated, when the heating unit is in operation. For example, the "active" external heat-distributor may be enclosed between the "passive" heat-distributor and the heater element, or the heating unit has only the heater element made with holes (internal heat distributor) and the passive heat-distributor.

As defined by accepted standards with respect to the specific application of maintaining the core temperature of a patient's body under anesthesia, to completely avoid the damage of burns to a patient's body, the temperature on a heating unit itself, mainly on its external surface, should not exceed 41°C. At the same time, the surface temperature of the patient's body should not exceed 38°C. Accordingly, the heat flow from the heating element to the patient's body should be carried out with the maximum temperature gradient of 3°C. Taking into account that several layers of materials with very low heat conductivity (air, tissue, polyethylene) have to be accommodated between the heat dissipating element and the body, the exclusive complication of this problem is evident. The present invention solves this problem by providing the heat-distributor element and thereby reducing the temperature of the external surface of the heater element at 3-4°C, while maintaining the required core temperature of the patient's body.

10

20

25

30

According to yet another aspects of the present invention, there are provided a heating device comprising an electrical heating unit configured as described above and a power source for supplying a required voltage to the heating unit; and a heating system comprising the heating unit, power source and a control unit.

The heating unit of the present invention can operate with a substantially low voltage supply, e.g., several tens of voltage, e.g., 12V and less. The power source may comprise a step-down transformer interconnected between the power network and the heating device. The power supply source may comprise and an accumulator unit. The latter may for example include two or more batteries, which

10

15

20

25

are selectively operable by a switching unit, so as to connect a selective one of the batteries to the heating element. Batteries may and may not be of a rechargeable type. If rechargeable batteries are used, the construction may be such that, when one of the batteries is in operation, another battery in the unit may be charged with a charging unit.

The heating unit may be accommodated inside a bed-sheet for covering or wrapping the patient's body or body part to be heated, wherein such a cover or wrap may be made of any suitable material. The heating element may be formed of several separate parts for heating selective segments of the patient's body, such as legs, arms, torso, back or abdomen.

The control unit may comprise a temperature sensor for measuring the core or body temperature, a processing and managing unit, and an indication unit, and is operable to provide continuous feedback loop control of the temperature of the body and of the operation of the temperature sensor, and to provide indication thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be carried out in practice, preferred embodiments will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

- Fig. 1 is a block diagram of a heating system utilizing a heating unit according to the invention;
- Figs. 2A to 2E illustrate five examples, respectively, of the heating unit of the present invention suitable to be used in the system of Fig. 1; and
- Fig. 3 is a schematic illustration of main functional components of the system of Fig. 1.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

Referring to Fig. 1, there is illustrated a heating system 10 comprising a heating device 12 that includes a heating unit 18 according to the invention

15

20

25

30

connectable to a power supply source 14; and a control unit 16. The construction of the control unit 16 does not form part of the present invention, and it may be of any known kind utilizing at least one temperature sensor, processors, contact and non-contact switches, etc. The power supply source 14 as a separate element is also known *per se* and therefore its construction and operation need not be specifically described, except to note that it operates to provide the normal operational mode of the heating unit 18 in accordance with instructions generated by the control unit 16.

Generally, the heating unit according to the invention is designed so as to generate the amount of heat required for heating an object (or part of an object) up to a desired temperature and to provide homogeneous temperature field within the heating object. To this end, the heating unit is designed so as to have an internal or external heat distributor.

In the present example of Fig. 1, the heating unit utilizes an external heat distributor. The heating unit 18 is thus composed of two elements 18A and 18B accommodated adjacent to each other in spaced-apart relationship, for example at a 1mm distance between them. The elements 18A and 18B are electrically insulated from each other, for example, by lamination of at least those surfaces of the elements by which they face each other by insulating layers such PVC, polypropylene, etc. The elements 18A and 18B have different surface areas and different resistance: the element 18A, that is to be connected to the power source when the device is in operation and is located farther away from the heated object, has relatively high resistance and relatively small surface area as compared to the element 18B, and serves as a heater element. The element 18B, that has relatively small resistance and relatively high surface area, is to be located closer to the object to be heated and may and may not be connected to the power source, and serves as a distributor of heat created by the heater element 18A to provide a substantially homogeneous temperature field within the heated object. Preferably, the surface area of the heat-distributor element 18B by which it faces the body is of about the size of the surface of the object to be heated, and is preferably no less than 2 times larger than the heat dissipating surface of the element 18A. The heat distributor

15

20

25

30

element 18B thus provides a "one-side" heat transfer (distribution) of the heat created by the element 18A.

The elements 18A and 18B are made from the same or different materials each with a specific resistivity in a range of about 0.01-0.10hm·mm²/m, e.g., aluminum, copper or iron foil. The heating unit 18 is thereby flat, flexible and light, and can be located inside a bed-sheet (of any suitable material) for covering the patient's body or body part to be heated. Generally, the elements 18A and 18B are mounted with respect to each other so as to provide good thermal contact between them, namely such that there are substantially no heat losses within the contact area. When the heating unit 18 is put in operation, the element 18B is located between the element 18A and the object to be heated, and serves as a distributor of heat created by the heater element 18A.

Reference is made to Figs. 2A-2C showing three different examples, respectively, of the implementation of the heating unit according to the invention. In heating units 118 and 218 of Fig. 2A and 2B, a "passive" heat distributor element is used (i.e., to be disconnected from the power source, when in the operation of the heating unit), while a heating unit 318 of Fig. 2C may utilize an "active" heat-distributor element.

The heating unit 118 (Fig. 2A) includes a heater element 118A in the form of a zigzag-like strip made of iron foil (ρ =0.10hm·mm²/m), and a heat-distributor element 18B that is a rectangular sheet made of aluminum foil (ρ =0.027 Ohm·mm²/m) with the 350mmx320mmx0.018mm dimensions. The strip 118A has a thickness δ =0.05mm, width b=15mm, and a total length L=2.6m. In this specific example, the resistance of the strip 118A is 0.30hm, and the 3V voltage supply thereto results in a current I=10A through the element 118A and heat power P=30W. The strip 118A is arranged such that it defines several pairs of spaced-apart parallel segments, generally at S, each of a length l=230mm, wherein each two adjacent segments S are connected by a segment S₀ of the strip of a length l0=25mm (the ratio l/l_0 being 9.2). In other words, the strip is folded such that the length l of each of the spaced-apart substantially parallel segments S is substantially

20

25

larger than the length l_0 of the strip segment S_0 between each two adjacent parallel segments. Hence, the arrangement of the strip 118A results in that electric currents flowing in the two adjacent segments S have equal magnitudes and opposite directions, and the fact that $l>>l_0$, results in the negligible (substantially zero) magnetic field in the vicinity of the heating unit 118.

The heating unit 218 of Fig. 2B comprises a sheet-like heat-distributor element 218B made of aluminum foil of a thickness of 0.018mm, and a serpentine-like strip 218A made of aluminum foil having a width b=10mm, thickness &=0.018mm, the total length L=9.77m and resistance R=1.40hm. The strip 218A is folded such that it defines a plurality of spaced-apart parallel identical segments S₁ (each of a length l₁=580mm) and a plurality of spaced-apart parallel identical segments S₂ (each of a length l₂=560mm), with a space between the adjacent segments S₁ and S₂ being a₁=10mm and a space between the two adjacent segments S₂ being a₂=23mm. Thus, the elements 218A and 218B made of the same material have different geometries resulting in different resistance values, and the arrangement of the strip 218A provides for compensating the magnetic field created by the electric current passage therethrough. By supplying 5,1V to the heater element, a current I=3.5A through the heater element and heat power P=18W are obtained.

Preferably, the dimensions of the heater element (e.g., strip) satisfy the following relationships:

$$l \ge k \cdot U_{heat} \cdot \sqrt{\frac{\delta}{\rho}} \qquad \qquad b \ge k \cdot I \cdot \sqrt{\frac{\rho}{\delta}}$$

Here, U_{heat} is the voltage that falls on the heater element; I is the current flowing therethrough; ρ is the specific resistivity of the heater element material; δ is the thickness of the heater element; k is a coefficient depending on the object to be heated and the required temperature, selected so as to satisfy the condition that electric power supplied to the heater element (heat power) is substantially equal to

20

30

power needed for heating a specific object to a required temperature. This approach for designing a heating element, aimed at providing an as low as desired temperature gradient between the temperature of the heat dissipating surface of the heating element and the required temperature of the object, has been developed by the inventor of the present application and is disclosed in U.S. Patent No. 6,483,990. The main idea of this technique consists of considering the relationship between the physical parameters (i.e., length, width, thickness and specific resistivity) of the heating element, and its electrical parameters (i.e., voltage and current). The physical parameters are dictated by the heating power W required for heating a specific object to a desired temperature, i.e., W=kS, where S is the area of the outer surface of the heating element through which the heating power W is dissipated (i.e., product of the length l and width b of the outer surface), and k is the coefficient depending on the object to be heated and the desired temperature. The electrical parameters are dictated by electric power, W'=UI, supplied to the heating strip, wherein U is the electric potential and I is the electric current passing through the heating element, which depends on the specific resistivity ρ of the selected heating element material. To facilitate the understanding of this idea, let us assume that the temperature gradient needs to be reduced. For this purpose, the value of k is appropriately increased, which automatically causes the surface area Sof the heating element to be increased. This, in turn, means that lower voltages should be supplied to the heating element, and this factor is used in selecting the electric conductive material with an appropriate specific resistivity.

In the example of Fig. 2C, the heating unit 318 is composed of heater and heat-distributor elements 318A and 318B made of the same material, e.g., aluminum, in the form of flexible sheets of equal perimeters. Here, however, the heater element 318B is formed with holes H (four spaced-apart arrays of holes in the present example) having the length of 10mm and the width of 6mm, defining aluminum segments S_1 and S_2 of dimensions b_1 =3mm and b_2 =6mm, respectively. The segments S_1 thus create the required resistance for the element 118A while the segments S_2 provides for better heat distribution (the so-called "internal heat

20

30

distributors"). The heater element 318B thus has a relatively reduced effective cross-section defined by the width of the segments S_1 between the holes. When the heat-distributor element is also connected to the power source, the electric currents in the two elements have the same magnitude and opposite directions. This can be obtained by connecting the heater element and the heat-distributor element in series to the common power source and placing one on top of the other.

The provision of holes is associated with the following. Heat created by the heater element should be transferred to the heat-distributor element, which should distribute this heat within its entire surface so as to achieve a homogeneous temperature field within the heated surface. Since the distributor should preferably be very thin (to make the device flexible), it would be difficult to transfer heat to high distances even when using aluminum or copper as a heat-distributor material (high heat conductivity material). For example, at a maximal thickness 0.014-0.018mm of the heat-distributor, heat can be effectively transferred ("effectively" meaning so as to maintain the homogeneity of the temperature field within the heated surface) to a distance of up to 4cm. Therefore, the distance between the projection of the active element that dissipates heat (heater element) onto the passive element that distributes this heat (heat-distributor element) and any other location on the heat-distributor where the homogeneous temperature field is to be maintained, should be up to 3-4cm (preferably 2-3cm). Hence, in order to provide the minimum of this distance when both the heater and the heat-distributor elements are sheets of substantially the same perimeter, the heater element is made with a plurality of holes such that the effective cross-section of the heater element provides the required resistance of the heater element to meet the requirements of power to be supplied to the heater element. By this, the entire surface of the heatdistributor is "filled" by the heat-element material, i.e., the maximal distance between the effective segments of the heater and distributor is reduced to the order of the hole's dimension (about 3-4mm). Thus, generally speaking, the provision of holes is to provide alternation of heat dissipating segments (segments of lower surface area) with heat distributing segments (segments of higher surface area). A

15

20

25

heating element with holes thus presents connected in series elements of high resistance (narrow segments) and elements of low resistance (wide segments), the narrow elements providing heat generation and wide segments providing the distribution of this heat, thereby sometimes eliminating the need for external heat diffuser.

It should be noted although not specifically shown that both the heater element and the heat-distributor element may be strips, e.g., folded in a ripple-like fashion, provided the heat-distributor element has a larger surface area than the heater element. Additionally, the heating unit may be composed of a heater element, an "active" heat-distributor (connected to the power source), and an additional "passive" heat-distributor element (disconnected from the power source) that is to be located closer to the object to be heated.

It should be noted that since the electric heating does not utilize liquid transfer or gaseous transfer at all, it is a simple task to divide the entire heating unit into several parts of equal dimensions and equal power, taking into account that the same power is required for heating both arms of a patient and his leg, in accordance with their dimensions. Therefore, each part of the heating unit may form a heater device with the power of 12W, 6W being needed for each patient's arm.

Experiments of heating elements-with-holes made of various materials, such as aluminum, copper, iron-based alloys, utilizing the holes of various geometries (circular, rectangular, elliptical), have shown the following main advantages of these heating elements:

- (1) The use of these heating elements enables to significantly reduce the heating element length. This is important when creating a heating unit of limited dimensions at a fixed power to meet the requirements of a specific application.
- (2) The use of heating elements with holes enables to obtain homogeneous temperature field without the use of a heat diffuser (heat distributor) as a separate element (external heat diffuser). If compensation of an electromagnetic field is also required, the heating element with holes can be a strip arranged as described above

20

25

so as to provide for compensating the magnetic field created by the electric current passage therethrough.

Figs. 2D and 2E exemplify heating units 418 and 518 each utilizing a heater element formed with holes H (with no heat distributor element as a separate element). These heater elements may be made of any electrically conductive material, such as transformer steel, stainless steel, aluminum foil, copper, etc. The holes are arranged such that an array of holes extends along the electric current passage through the heater element, defined by the application of voltage to the heater element.

The heating unit 418 comprises the heater element 420, e.g., made of aluminum and designed similar to the element 318B of Fig. 2C, namely, including four spaced-apart arrays of holes H having the length of 10mm and the width of 6mm, defining aluminum segments S_1 and S_2 of dimensions b_1 =3mm and b_2 =6mm, respectively. The segments S_1 thus create the required resistance for the element 318B while the segments S_2 provide for better heat distribution ("internal heat distributors"). The heater element 318B thus has a relatively reduced effective cross-section defined by the width of the segments S_1 between the holes.

The heating unit 518 comprises the heater element 520 in the form of a zigzag-like strip (similar to that of Figs. 2B or 2C). The strip 520 is folded such that it defines several pairs of spaced-apart parallel segments, generally at G, of a certain length l, wherein each two adjacent segments G are connected by a segment G_0 of the strip of a length l_0 significantly smaller than the length l (e.g., l=230mm and $l_0=25$ mm, the ratio l/l_0 being 9.2). In other words, the strip is folded such that the length l of each of the spaced-apart substantially parallel segments G is substantially larger than the length l_0 of the strip segment G_0 between each two adjacent parallel segments G. Hence, the arrangement of the strip 520 results in that electric currents flowing in the two adjacent segments G have equal magnitudes and opposite directions, and the fact that $l>>l_0$, results in the practically negligible (substantially zero) magnetic field in the vicinity of the heating unit 518. Additionally, each of the segments G (or the entire strip 520) is formed with holes,

10

20

25

for example similar to that of the heater element 420 of Fig. 2D. Thus, heater element segments defining the holes serve for creating the required resistance for the element 520 and providing better heat distribution ("internal heat distributors"), while the arrangement of the strip 520 provides for compensating the magnetic field created by the electric current passage therethrough.

Generally, the shape of holes in the heater element depends solely on the requirement to the heater element size (e.g., its length): the smaller the dimension b_1 of the segment S_1 , the shorter the heater element needed for dissipating a predetermined power. The smaller part of the heater element material through which the electric current flows (the narrow segments) dissipates heat (due to higher resistance), while the other part (wider segments) distributes this heat. Hence, the segments S_1 define the required power created by the heater element, while segments S_2 define the heat diffusion. Direct contact between the segments S_1 and S_2 results in diffusion of heat dissipated by the segments S_1 . The use of heater elements with holes without any external heat distributor enables to create super-thin (about 0.2mm and less) and precise heater elements with the temperature gradient within the heater element of about 0.5°C and less.

The present invention can advantageously be used to prevent and treat hypothermia and provide warmth to cold or shivering patients. In addition, the invention can be used whenever conditions exist that could cause patients to become cold/hypothermic. The invention can be used in operating rooms, recovery rooms, intensive care units, labor and delivery, emergency rooms, ships, aircrafts, long term care facilities, home health-care and other areas where a patient needs to be warmed by medical professionals. The invention can be used for heating surfaces of any size and body kind, in both humans and animals. In one specific, but non-limiting example, the present invention is used for heating a part of the patient's body up to 38° (the skin temperature). Power supplied to the heater element is 18W. The heater element has the heat dissipating surface area of $40x60cm^2$. The working temperature of the heater element is 39°, thus providing a

15

20

25

30

1° temperature gradient between the working temperature of the heat dissipating surface and the required temperature of the heated body part.

As indicated above, a power supply source suitable to be used in the present invention may be of any known kind, and is selected in order to supply a required voltage to the heating unit and to meet the requirements of a specific application. The following is the description of one specific, but not-limiting example of the power supply source suitable to be used in the device of the present invention.

In one specific but non-limiting example, the power supply source comprises an accumulator unit including two batteries, each selectively chargeable by a standard charging unit including a step-down transformer. Preferably, the power supply source activates the control unit and the heating unit and includes the first and second power supply units. For example, the first power supply provides a 6V voltage to the heating unit and the second power supply provides a 24V to the control unit. Additionally, each power supply charges two 6V batteries that activate the control unit and the heating unit when power out should occur. Each of the power supply units is adjusted to power that is required to recharge the batteries. The 6V power supply is adjusted to 7V DC and the 24V supply is adjusted to 27V DC. Since the power required for the heating unit is lower than the supplied power, a serial diode can be used that decreases the supplied power to the desired value. The power supply units may operate in a phase control manner. This technique is based on the principle of a component that operates as a switch. In this case, a SCR connected to the outlet of the entrance transformer reduces the power. The SCR is connected to a low AC power controlled by a control electronic card, which commands the SCR to start operation in a certain ignition angle dictating the outlet power. In case of low input power or over loading of the power supply, the control card commands the SCR to enlarge the ignition angle and by this, it corrects the power and returns the power to its original nominal value. Each power supply incorporates an internal shunt, which measures the current to protect the power supply against short-circuits or over loading. The shunt also performs current limitation.

20

25

30

The use of an accumulator as a power supply source eliminates the creation of an electromagnetic field, due to the absence of the alternating current component. The accumulator provides direct voltage output in which the alternating component is absent, which results in the absence of electric current oscillations, and thereby the absence of the electromagnetic field. As for a magnetic field created by the electric current passing through the heater element, it can be reduced as described above.

Reference is made to Fig. 3, exemplifying the functional elements of the system 10 of Fig. 1. In this specific but non-limiting example, the power supply source 14 utilizes an accumulator unit 20 including two batteries B_1 and B_2 , each selectively chargeable by a standard charging unit 22 typically including a step-down transformer (not shown). It should, however, be understood that a power supply source of any other suitable kind can be used. The charging unit 22 is interconnected between a power network and an analyzing unit 24, which operates to switch between the batteries B_1 and B_2 , so as to selectively connect one of them (which is charged) to the heating unit 18 (at least the heater element thereof). A connecting unit 26 operates to connect/disconnect the heating unit 18 to the accumulator unit 20. A processing and managing unit 28 is provided, being interconnected between the heating unit 18 and the connecting unit 26, and being connected to an indication unit 30.

The processing and managing unit 28 performs the following functions: it controls the operation of appropriately provided one or more temperature sensors (not shown) that generate data indicative of the current core temperature of the patient's body; analyzes the current temperature of the patient's body; controls the operations of the switching and connecting units 24 and 26. The indication unit 30 provides indication of the operational state of the other units, and the temperature of the patient's body.

When designing the above circuit, the following important operational requirements are considered: complete electrical safety for both the patient and medical personnel; continuous control of the temperature level of the patient's

body; control of breaking of the temperature sensor circuit associated with means involved in the anesthesia process and with the external temperature sensors; continuous control of the extent of discharging of the battery with the possibility of switching to a reserve battery; reduction as much as possible in the signal-noise level with respect to other electronic equipment.

5

10

20

25

30

When putting the system of the present invention into operation, an indication that the system is connected to a power network is provided by any suitable means, for example, a lamp. Other suitable indicators, e.g., lamps, provide an indication that the fuses of the primary coil of the step-down transformer are in good condition. The voltage of 220V is supplied to the transformer, and the lowered alternating voltage of about 7V is provided on the secondary coil of the transformer. Alternating voltage is supplied from the secondary coil onto a diode bridge, and then onto a voltage stabilizer. As a result, an output DC voltage of about 6V is provided at the output of the charging unit 22. This voltage output is aimed at recharging the batteries, either battery $\mathbf{B_1}$ or $\mathbf{B_2}$, depending on the extent of the battery discharge.

As to which battery should be put in operation and which one should be recharged, this is determined by the analyzing scheme in the analyzing unit 24. During the analyzing procedure, the unit 24 generates a signal indicative of the switching procedure, in response to which a transistor (not shown) in the processing and managing unit 28 is closed, which means that the current flow in the heating strip is halted, and an electrical circuit between the units 24 and 26 is disconnected. This is implemented by mechanical means, such as relay contacts. This having been done, that battery which is more discharged among the two, is connected to the charging unit 22 by switches (relay contacts), while the other battery is connected to the circuit line operating for heating. After the completeness of the process of switching between the batteries, control signals are sequentially generated in the processing and managing unit 28, so as to put the heating device into operation, namely, the relay contacts are closed and the transistor in the unit 28 is completely opened. Then, the unit 28 is completely put in operation.

10

20

25

30

As indicated above, the presence of the temperature sensors is considered. The processing and managing unit 28 continuously controls the magnitude of the temperature and controls the situation of accidentally breaking the temperature sensors. Concurrently with this control, the indication unit 30 proves information about the temperature value exposed to an authorized person.

Following are several processes that may occur during the operation in an operating room:

- 1. The temperature of the patient's body exceeds the given value. In this case, a corresponding signal is generated in the processing and managing unit 28, so as to lock the transistor. Accordingly, the relay contacts are disconnected. The indication unit 30 provides a signal indicative of the fact that the heating process is halted. The unit 28 continues to control the decrease in the temperature of the patient's body, and upon detecting that the temperature is less that the defined threshold, generates corresponding signals so as to switch on the heating process (the relay contacts are closed and the transistor is opened). The indication unit 30 provides indication to the fact that the heating is turned on.
- 2. The temperature of the patient's body does not reach the given value, and an indication signal indicative of switching between the batteries is generated by the unit 30. In this case, the processing and managing unit 28 generates a sequence of signals aimed at disconnecting the heating unit 18 from the battery, and operates the analyzing unit 24 for switching between the batteries. The units 24 and 28 operate together so as to allow the switching process. After switching to the correct battery, the heating unit is supplied with the required voltage so as to perform the heating process.

In the specific example, the electrical conditions are as follows:

Electric voltage of about 220V is supplied to the accumulator unit 22 through screened wires with doubled electrical insulation. The fuses are mounted in two phases of the primary network of the transformer. Human access to the fuses without the use of a special tool is completely avoided. The transformer is of a down step torroidal kind, and the strengthened double insulation is provided

between its primary and secondary windings and between the primary winding of the magnetic core. There is no such moment in time when the heating unit is in its operating position during the switching between the batteries. In other words, when the processing and managing unit 28 operates to provide switching between the batteries, the heating unit 18 is previously disconnected and maintained in this position during the entire re-switching process, i.e., the heating unit is mechanically (and electrically) disconnected from the accumulator unit 20 and from the charging unit 22. Thus, only one, charged battery is always electrically connected to the heating unit, while being at that time disconnected from the charging unit 22 (i.e., from the power network).

It should be noted that the present invention can generally be used with a power source of any suitable kind, and is not limited to the above examples.

10

15

20

Thus, the present invention provides a thin and flexible (possibly flat) heating unit that enables an as low as desired temperature gradient between the temperature of the surface of the heat dissipating surface in the heating unit and that of an object to be heated, and reduction of a magnetic field created by the heating unit when in operation. The provision of the heat-distributor element enables to provide the uniform distribution of heat flow directed towards the object to be heated (homogeneous temperature field within the heated body surface), and to reduce the heat flow reaching the body.

Those skilled in the art will readily appreciate that various modifications and changes can be applied to the preferred embodiment of the invention as hereinbefore exemplified without departing from its scope defined in and by the appended claims.